



Use of a Patient Navigator to Increase Colorectal Cancer Screening in an Urban Neighborhood Health Clinic

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ABSTRACT Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States. Racial disparities in CRC incidence and mortality have been well documented. In addition, lower rates of CRC screening among ethnic minorities have been reported. Therefore, we tested the effectiveness of a patient navigator (PN) in increasing compliance with CRC screening in a minority community health setting. Men and women aged 50 or older attending a primary care practice were enrolled if they had not had a fecal occult blood test within the past year, a sigmoidoscopy or barium enema within the past 3–5 years, or a colonoscopy within the past 10 years. Participants were randomly assigned either to receive navigator services (PN+) or not to receive navigator services (PN–). There were no demographic differences between the two groups. Within 6 months of physician recommendation, 15.8% in the PN+ group had complied with an endoscopic examination, compared with only 5% in the PN– group ($P=.019$). The PN+ group also demonstrated higher rates of fecal occult blood test completion (42.1% vs. 25%, $P=.086$). Thus, a PN system successfully increases CRC screening rates among a predominantly minority population of low socioeconomic status.

KEYWORDS Colorectal cancer screening, Fecal occult blood test, Flexible sigmoidoscopy, Urban health.

INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States.¹ It has been estimated that over 147,000 new cases of CRC would occur in 2003, with over 57,000 deaths due to this disease.² CRC screening tests, which have now been demonstrated to save lives, are still, unfortunately, woefully underutilized.³ Racial disparities in CRC incidence and mortality have been well documented. CRC incidence and mortality is highest for African American men and women compared with White, Hispanic, American Indian, and Asian individuals in the United States (Surveillance, Epidemiology, and End Results 1973–1996; http://seer.cancer.gov/csr/1973_1996/colorect.pdf). On the basis of 1997 Surveillance, Epidemiology, and End Results data, Hispanic men and women have a

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lower incidence of and mortality from CRC compared with Caucasians and African Americans.^{4,5} However, because many Hispanic Americans are immigrants from countries of lower CRC risk, it is anticipated that as they remain in the United States, and with subsequent generations, their CRC risk will rise to the level that is currently prevalent in the general US population.

Racial disparities also exist with respect to CRC screening. The disparity between screening rates for African American and White individuals is in part explained by the generally lower adherence to cancer screening tests among African American men and women. According to the Behavioral Risk Factor Surveillance System data from the National Center for Chronic Disease Prevention and Health Promotion, only 25.9% of African Americans in the United States who are over the age of 50 report ever having used a fecal occult blood test (FOBT) kit and 30% have ever reported having a flexible sigmoidoscopy (FS) and/or colonoscopy.³ Even lower rates are reported for Hispanic men and women over age 50; only 20% have ever completed a FOBT home test kit and 25% have ever had an FS and/or colonoscopy.³

The lower rate of CRC screening among ethnic minorities is unfortunate given the substantial evidence that regular screening can successfully reduce mortality from CRC. Four prospective randomized controlled trials conducted in the United States and in Europe have demonstrated that CRC mortality can be reduced by approximately 33% if FOBT is performed annually and by 15–18% if it is performed every other year.^{6–9} Although there are no prospective controlled studies of screening FS to date, retrospective case-control studies indicate that sigmoidoscopy can reduce deaths due to cancers within reach of the instrument by approximately 60–80%.^{9–11}

The East Harlem Partnership for Cancer Awareness was established to help identify barriers to cancer screening in minority, medically underserved people in the East Harlem community. Information obtained during five focus group sessions with 43 African American and Hispanic men and women suggested that one possible barrier to CRC screening in this population is the difficulty patients have trying to navigate the health care system. Therefore, we reasoned that a patient navigator (PN) system might enhance the completion of CRC screening tests.

A PN is an individual who can work individually with patients to both educate and help them negotiate the medical system. PN programs have been shown to increase screening rates for prostate and breast cancer. In one study of prostate cancer screening, over 1,500 men were recruited from community sites (churches, barber-shops, housing projects, etc.).¹² Subjects were then divided into groups to receive one of four educational interventions: traditional, peer educator, client navigator, or combination. The traditional method involved educating patients about prostate cancer. The peer educator intervention included the traditional method along with a personal testimony concerning the importance of going for screening by a man who could be considered a “peer” of the sample. The client navigator approach included the traditional method along with a social worker who “navigated” the health care system for the sample to participate in screening. The navigator provided written reminders, telephone calls, and/or transportation to their subjects, encouraging participation in prostate cancer screening. The combination method included the traditional, peer educator, and client navigator intervention. Of the four educational interventions, two were significant predictors of participation in prostate cancer screening: the client navigator ($P=.000$, $OR=2.039$) and the combination method ($P=.000$, $OR=2.324$).

Other investigators implemented a PN system in a medically underserved community in the Bronx, New York, to assist women in the follow up of significant abnormalities on mammography.¹³ The population in this study was primarily Black and Hispanic, uninsured, and of low educational status. The PN contacted all women through telephone, ensured timely appointments, walked women through diagnostic tests, ensured follow up on all referrals, and checked to see whether women kept their various appointments. Compliance rates with subsequent biopsy of lesions for women who received navigation were 100%.

The success of the navigator model is further illustrated by the Harlem Cancer Education and Demonstration Project, which functioned as a patient support program.¹⁴ The target group was low income, predominantly minority (over 90% Black and Hispanic) individuals of low educational status. The Harlem Cancer Education and Demonstration Project used a PN program to help address barriers that underserved individuals have in trying to obtain follow-up services once an abnormal breast cancer screening finding or an established cancer diagnosis was made. The navigators in this model, although not volunteers, were individuals with low salaries and limited training and experience who learned through on-the-job training, monitoring, and program participation. The navigator support was initiated at the time that the patient received abnormal test results, to ensure adequate clinical follow up of these results. The navigators did not function as peer educators and did not receive formal education. In this program, the navigator met with the patient after referral, explored barriers faced by the patient, and reported problems at staff meetings where possible solutions would be generated. The need for patient navigation was so evident by the overwhelming demand and numerous referrals that a second, bilingual PN was hired. Although there were no significant differences between the two groups in whether they had a breast biopsy, 85.7% of those navigated completed recommended biopsies, compared to only 56.5% of nonnavigated patients, with the trend suggesting that navigation may have facilitated the completion of the recommended biopsies.¹⁴ In addition, for those who completed biopsies, the navigated patients completed the biopsy in significantly less time than the nonnavigated patients.

Given these successes of patient navigation, and the paucity of data regarding this approach for CRC screening, the main goal of this study was to test whether a PN program, in addition to physician recommendation, could help overcome the barriers that medically underserved people might have in trying to obtain clinical CRC screening services. We hypothesized that a PN who is culturally sensitive to the needs of the community would enhance participation in CRC screening over and above that which can be accomplished by physician recommendation alone.

METHODS

This study was designed as a prospective clinical trial intended to determine whether a PN would enhance CRC screening participation beyond physician recommendation alone in a neighborhood health care setting. Institutional Review Board approval was obtained before conducting this study.

Subjects

Participants were identified from among patients attending a primary care practice in East Harlem, New York City, between January and May 2002. The practice is a federally qualified health center providing over 40,000 visits annually to over 9,000

individuals. It has a full range of primary care services and is staffed by permanent physicians, ensuring continuity of care. Eligible subjects included men and women aged 50 or older who (1) had not had an FOBT within the past year, (2) had not had an FS or barium enema within the past 3–5 years, and (3) had not had a colonoscopy within the past 10 years. Charts of all scheduled patients were successively reviewed for eligibility, and the research assistant (RA) approached prospective participants. One hundred twenty-five people were approached, and 88 (70%) agreed to participate (Fig. 1). The 37 patients who refused to participate did not differ by gender distribution from those who agreed. Of the 88 who agreed to participate, 4 were later found to be ineligible because of previous CRC screening and 6 were lost to follow up (1 died and 5 medical charts could not be located). Thus, the study group consisted of 78 presumably asymptomatic participants who were then randomized into two groups: 38 people who received patient navigation services (PN+ group) and 40 who did not receive patient navigation services (PN– group). Interviews and informed consent were administered in either English or Spanish, depending on the participant’s preference. At the time of recruitment, a 17-item sociodemographic questionnaire was also completed.

FOBT cards were placed in the charts of all participants both to serve as a cue to the physician and to ensure that the physician was blinded to the patient’s study state. All participants were asked by their physician to complete FOBT cards and were recommended to undergo endoscopic screening (either FS or colonoscopy). We did not, however, assess whether all participants received a recommendation for endoscopic screening from their physician. Participants in the PN+ group were then

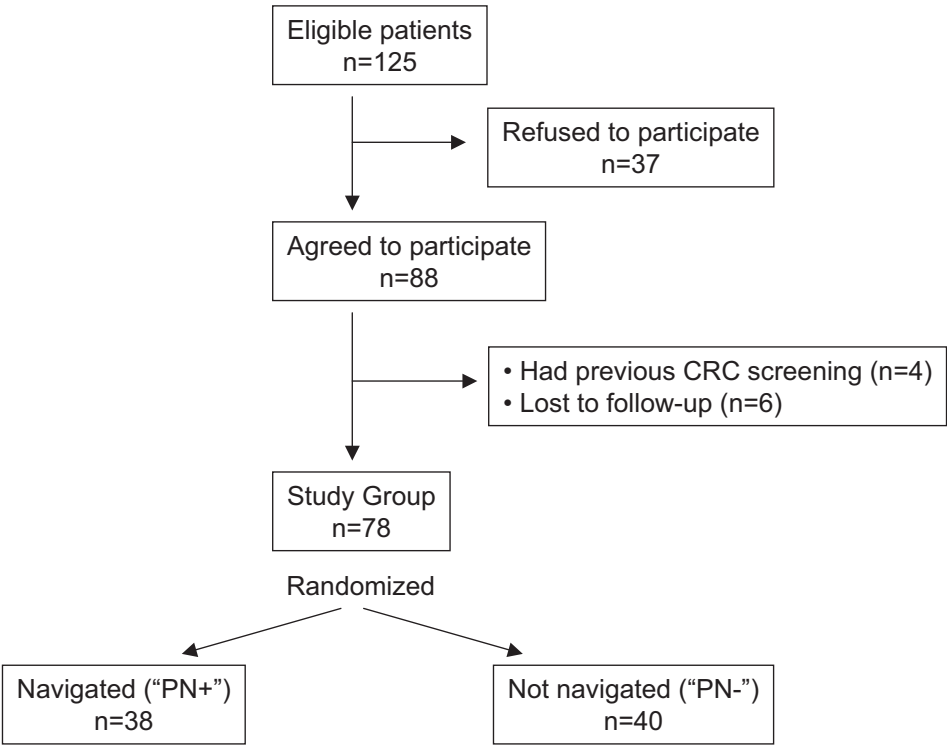


FIGURE 1. Selection and randomization of subjects.

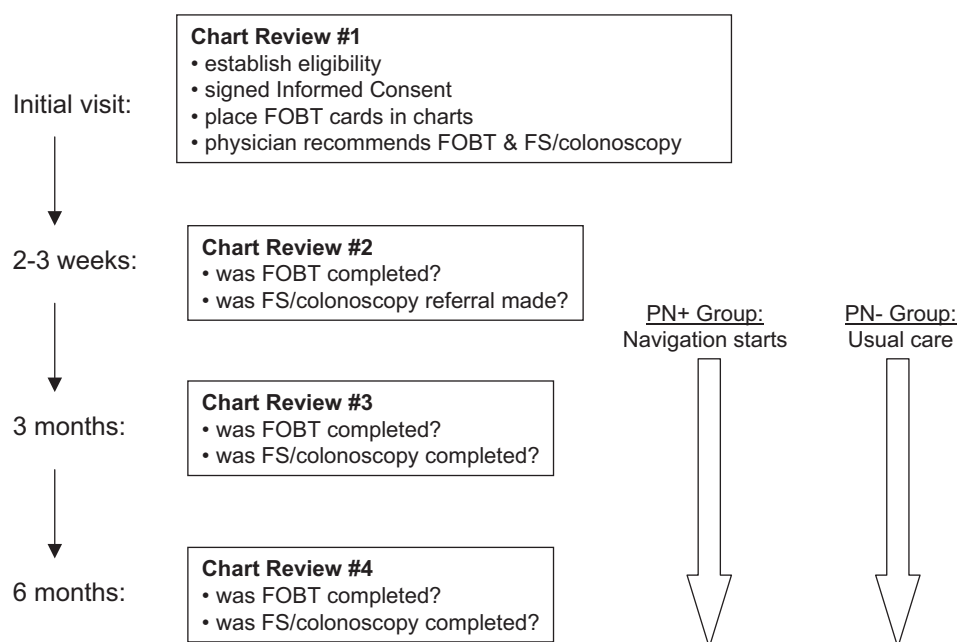


FIGURE 2. Schema of chart reviews.

assigned to the PN for assistance with completing the screening process, including the FOBT cards and endoscopic procedures that had been recommended by their physician (Fig. 2). The PN provided written reminders, telephone calls, and/or scheduling assistance to the participants, encouraging participation in CRC screening. One of the general functions of the PN was to provide support and advocacy for the participant and assist with patient education regarding CRC risks, prevention, and other relevant information. The PN coordinated with health care facilities to schedule appointments for FS as per the physician's request. The PN was from a similar cultural background to most participants because we expected that similarity of cultural patterns, values, experiences, and problems would likely enhance the participant's identification and comfort with the navigator.

Study Design

All participants in the study group were followed to determine whether they indeed had completed CRC screening tests. Completion of CRC screening tests was determined by a series of sequential chart reviews conducted in a nonblinded fashion by the PN/RA (Fig. 2). Following the completion of the informed consent, the first chart review confirmed the participant's eligibility. At this time, FOBT cards were placed in the reviewed charts. A second chart review took place 2–3 weeks after the initial interview and medical visit. FOBT completion as well as referral for FS or colonoscopy was recorded. Participants in the PN+ group who had not returned their FOBT cards were also called during this period and reminded of their need to complete their screening for CRC and given any assistance they needed. The third chart review was performed 3 months after the initial contact. During this time, FOBT completion as well as FS or colonoscopy completion was noted. After 6

months, the charts of all participants were reviewed for a fourth and final time to assess FOBT, FS, and/or colonoscopy completion.

Navigation

The RA served as the PN. She contacted the PN+ subjects 2–3 weeks after the initial contact to educate the participant about any additional information on both screening techniques and to begin navigation services. During the telephone call, the navigator inquired whether the participant had a scheduled appointment for his or her endoscopic examination as well as the status of the FOBT card completion. This served to identify those participants who made appointments before receiving navigator services. If necessary, the PN reviewed the collection technique and return procedure for FOBT cards. At this time, she addressed any barriers that the participant described with regard to collecting the specimens. The PN and participant would then set a date for when the participant intended to deliver the cards to his or her physician. Two days after the scheduled date, the PN would contact the participant again to determine whether the specimens had been returned to the physician and checked. If necessary, the PN addressed any problems or concerns, including lost cards or lack of understanding about the test.

If the participant did not schedule an appointment for FS, the PN reminded the participant that the physician referred him or her for an FS. The PN would then ask the participant whether he or she was interested in having an FS. If the patient said “yes,” she or he was assisted in scheduling an appointment. If the participant said “no,” the barriers that prevented that participant from completing the recommended screening procedure were recorded. Once the appointment was scheduled, the PN would call the participant 2 days before the FS to remind him or her of the scheduled procedure. The PN addressed further concerns that the participant might have regarding bowel preparation before the procedure, the protocol during the procedure, and expectations after the procedure. A gastroenterologist (S.H.I.) addressed any medically related concerns, problems, or questions. The PN called the participant after the date of the scheduled screening procedure and inquired whether he or she had the procedure done. If the procedure had not been completed, the PN would assess the situation, and any barriers or problems were discussed and resolved, if possible.

Data Analysis

Data were entered and statistical analyses performed by using SPSS (version 11.0 for Windows). Descriptive statistics were generated on all study variables. Bivariate analyses were conducted using the chi-square and Fisher exact tests for categorical data. The Student unpaired *t* test was applied to continuous data. Interval level scale variables were tested for homogeneity of variance. Findings with a *P* value <.05 (two-sided) were deemed statistically significant.

RESULTS

As summarized in Table 1, the PN+ and PN– groups did not differ by any sociodemographic characteristic. The mean age was 61.2 years. Similar to the demographics of this clinic population, 74.4% of all participants were female, and 82.1% were Hispanic (46.2% completed the assessments in Spanish). Approximately 29.5% reported being married or living as married. Consistent with this low-socioeconomic clinic population, only 11.5% had at least a high-school degree, two thirds had an

TABLE 1. Sociodemographics of the study population

Variable	PN+ group	PN– group	Overall	Significance
Age (mean \pm SD)	61.1 \pm 7.2	61.3 \pm 8.4	61.2 \pm 7.8	n.s.
Gender (% female)	76.3	72.5	74.4	n.s.
Ethnicity (% Hispanic)	78.9	85.0	82.1	n.s.
Language (% English)	55.3	37.5	46.2	n.s.
Marital status (% married)	26.3	32.5	29.5	n.s.
Education level (% at least high-school degree)	13.2	10.0	11.5	n.s.
Annual income (% <\$10,000)	72.2	64.1	68.0	n.s.
Employed (% yes)	7.9	10.0	9.0	n.s.
Years living in USA (mean \pm SD)	40.6 \pm 17.6	34.2 \pm 20.4	37.3 \pm 19.2	n.s.
Have a primary care provider (% yes)	97.4	92.5	94.9	n.s.
Have public health insurance (% yes)	68.5	70.0	69.3	n.s.
Family history cancer (% yes)	36.8	38.5	37.7	n.s.

TABLE 2. Adherence to screening

Variable	PN+ group	PN– group	Significance
Completed FOBT after 3 weeks (before navigation) (% yes)	26.3	17.5	n.s.
Completed FOBT after 3 months (% yes)	42.1	25.0	0.086 (n.s.)
Had endoscopy appointment at 3 months (%)	18.4	0	0.005
Completed endoscopy at 3 months (%)	15.8	5.0	0.115 (n.s.)
Completed endoscopy at 6 months (%)	23.7	5.0	0.019

FOBT, fecal occult blood test.

annual income under \$10,000, and fewer than 10% were employed, despite living in the United States for an average of 37.3 years. Nonetheless, the vast majority had a primary health care provider. Over two thirds had some form of public insurance (Medicare, Medicaid, or both). Over one third reported a family history of cancer.

The findings for CRC screening adherence are summarized in Table 2. Following their initial visit, at the 3-week chart review (during which no navigation services had been provided), no significant differences were noted in FOBT completion (26.3% vs. 17.5% in PN+ and PN– groups, respectively). However, at the 3-month chart review, FOBT was completed by 42.1% of those in the PN+ group compared with only 25% in the PN– group ($P=.086$). At that time, 18.4% of the PN+ had made an endoscopy appointment, compared with none in the PN– group ($P=.005$), and 15.8% of the PN+ group completed their endoscopic examination, compared with only 5% of the PN– (approaches trend; $P=.115$). Importantly, by the time of the final chart review 6 months after enrollment, 23.7% of the PN+ group had completed an endoscopic examination, compared with only 5% of the PN– group ($P<.02$).

DISCUSSION

Our rationale for pursuing this line of investigation is based on two observations. First, traditional interventions that have relied purely on standardized educational interventions have not substantially increased participation in cancer screening. Second,

PN programs have successfully enhanced screening for other types of cancers, as described above. Because little is known about the utility of a PN system for CRC screening, we decided to investigate this approach in patients who were recommended by their physician to undergo CRC screening. Unlike screening guidelines for other cancers, CRC screening guidelines permit the physician and patient to choose from several alternatives. The American Cancer Society recommends that asymptomatic, average-risk individuals over age 50 should undergo one of the following: (1) FOBT annually, (2) FS every 5 years, (3) FOBT annually plus FS every 5 years, (4) colonoscopy every 10 years, or (5) barium enema every 5 years. Although the availability to choose among several screening options may appeal to some, it can also be a source of confusion or lack of compliance on the part of the physician and patient.

We reasoned that if a PN system was effective, it might serve as a useful adjunct to reduce the complexities of CRC screening. We focused our efforts on average-risk subjects who were eligible for CRC screening. In keeping with the navigator studies cited above, our patients were also predominantly minority (Hispanic), urban, and of low socioeconomic status. By using a primary care clinic as our portal of entry, we eliminated the barrier of subjects not having a physician.

Our findings demonstrate that within 6 months after physician recommendation for CRC screening, a PN system was effective at ensuring that significantly more patients received CRC screening by endoscopy. This finding is important because endoscopic screening is considered superior to FOBT alone for reducing CRC mortality. That significantly more patients in the PN+ group had an appointment for endoscopy at 3 months further substantiates the usefulness of the PN approach. In addition, the PN+ group showed a trend toward increased completion of FOBT cards after 3 months, although this trend did not reach statistical significance. These findings therefore suggest that in a predominantly poor, urban, minority population, PNs can have a positive impact on CRC screening, with the potential for reducing the mortality from CRC.

Despite this apparent success, it is worth noting several factors. First, although the navigated group demonstrated higher rates of FOBT and endoscopic screening, their rates were still quite low and not much higher than those reported in the Behavioral Risk Factor Surveillance System study. Obviously, other barriers also remain in this population. Other factors to consider in our study are the relatively small sample size, the lack of documentation of physician recommendation, and the use of one clinical site. Nonetheless, the higher rates of CRC test completion among the PN+ group—despite the modest sample size—support the notion that a PN approach will be a useful adjunct to enhance CRC screening among minority individuals.

In keeping with previous studies utilizing PNs, we selected a PN who was from a similar ethnic background and who lived in the community from which we were recruiting, so that she would be familiar with the community's needs, organizations, and leaders and would therefore be more culturally sensitive. Culturally sensitive community-based approaches are more effective in minority populations than traditional approaches.^{15,16} Besides addressing issues of cultural sensitivity, our research group is beginning to explore new approaches to overcoming organizational barriers to endoscopic screening in this patient population.

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